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XIII. SUMMARY OF SAFETY AND EFFECTIVENESS**Baxter****MAY 22 1996****510(k) SUMMARY OF SAFETY AND EFFECTIVENESS****Jackson-Pratt Gold™ Wound Drains**

Manufacturer: Baxter Healthcare Corporation of Puerto Rico
Surgical Group
State Road 402, Km 1.2
Añasco, Puerto Rico 00610

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Date Summary Prepared: January, 1996

Product Trade Name: Jackson-Pratt Gold™ Wound Drains

Common Name: Surgical Wound Drain

Classification: Apparatus, Suction, Single Patient Use, Non-Powered

Predicate Devices: Jackson-Pratt® Wound Drains
Atrium PDR™ Thoracic Catheter

Description: The Jackson-Pratt Gold™ Wound Drains are made of polyvinyl chloride or silicone in a variety of sizes and are offered sterile.

Intended Use: These drains are used in conjunction with non-powered single patient, portable suction apparatus. The drains provide a means to conduct fluids from a surgical wound via suction drainage.